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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/882,435 06/25/97 HOXIE

J 9596-11U1

PANITCH SCHWARZE JACOBS & NADEL  
ONE COMMERCE SQUARE  
2005 MARKET SQUARE  
22ND FLOOR  
PHILADELPHIA PA 19103

HM21/0522

EXAMINER

NELSON, B

ART UNIT

PAPER NUMBER

1648

DATE MAILED:

05/22/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No. <b>08/882,435</b>	Applicant(s) <b>James A. Hoxie</b>
	Examiner <b>Brett Nelson</b>	Group Art Unit <b>1648</b>

Responsive to communication(s) filed on Apr 6, 1998

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 1-24 is/are pending in the application.

Of the above, claim(s) 11-24 is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 1-10 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 9

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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**DETAILED ACTION**

1. Applicant's election without traverse of Group I, claims 1-10 in Paper No. 10 is acknowledged. Upon further consideration it is determined that the election of species requirement will be withdrawn. Therefore, claims 11-24 are withdrawn as being drawn to a non-elected invention and claims 1-10 are under consideration.

*Priority*

2. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, applicant claims priority back to Jun. 25, 1996 while the specification incorporates references published in 1997 (see page 2, lines 5-10). Therefore, the instant specification appears to contain information which is not supported in the priority documents and the priority date will not be granted.

*Claim Rejections - 35 USC § 112*

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The language of the claims is not as precise as the subject matter permits such that one may reasonably know the metes and bounds of the claims. Claim 1 is indefinite because it is drawn to an anti-immunodeficiency virus antibody yet recites an antibody that binds to a cellular protein. Does applicant intend an anti-chemokine receptor protein antibody? Clarification is required to overcome this rejection.

*Claim Rejections - 35 USC § 102/103*

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-8 are rejected under 35 U.S.C. 102(a) or (b) as anticipated by Feng, et al. (Science, May 1996). The claims are drawn to an anti-immunodeficiency virus antibody which binds to a cellular protein. The protein is further limited to CXCR4, the virus is further limited to HIV 1, HIV 2, or SIV and the antibody is further limited to a synthetic antibody. Feng, et al.

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disclose antibodies to the cellular co-factor fusin (which is also known as CXCR4 protein) and teach that the antibodies blocked cell fusion and HIV infection with CD4 positive cells (abstract). The antibodies of Feng, et al. are the same as the claimed antibody. Since the Patent Office does not have the facilities for examining and comparing applicant's antibody with the antibodies of the prior art reference, the burden is upon applicants to show an unobvious distinction between the material structural and functional characteristics of the claimed antibody and the antibodies of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594. Feng, et al. anticipates the invention as claimed.

7. Claims 1-5, 8, and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Hoxie, et al. (J. Vir. , 1988). The claims are drawn to an anti-immunodeficiency virus antibody which binds to a cellular protein. The virus is further limited to HIV 1, HIV 2, or SIV and the antibody is further limited to a synthetic antibody or monoclonal antibody. Hoxie, et al. disclose monoclonal antibodies to HIV receptor proteins such as anti-CD4 antibodies and teach that the antibodies inhibited syncytia formation induced by HIV-1 (abstract and p. 2559). The antibodies of Hoxie, et al. are the same as the claimed antibody. Since the Patent Office does not have the facilities for examining and comparing applicant's antibody with the antibodies of the prior art reference, the burden is upon applicants to show an unobvious distinction between the material structural and functional characteristics of the claimed antibody and the antibodies of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594. Hoxie, et al. anticipates the invention as claimed.

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***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feng, et al. (Science, May 1996). The claims are drawn to an anti-immunodeficiency virus monoclonal antibody which binds to a cellular protein. The teachings of Feng, et al. are described above. Feng, et al. differ from the claimed invention by not specifically teaching monoclonal antibodies. However, Feng, et al., as stated above, disclose antibodies to the cellular co-factor fusin and teach that the antibodies blocked cell fusion and HIV infection with CD4 positive cells (abstract). It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to produce monoclonal antibodies to fusin or CXCR4. Producing monoclonal antibodies is routine and well within the level of skill in the art. It would have been expected, barring evidence to the contrary, that an anti-fusin monoclonal antibody would effectively prevent cell fusion and HIV infection *in vitro*.

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10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Cohen (Science, May 1996) which appears to disclose that Feng, et al. first disclosed fusin as an HIV cofactor.

11. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Examiner Brett Nelson, Art Unit 1648 and should be marked "OFFICIAL" for entry into prosecution history or "DRAFT" for consideration by the examiner without entry. The Art Unit 1648 FAX telephone number is (703)308-4426. FAX machines will be available to receive transmissions 24 hours a day. In compliance with 1096 OG 30, the filing date accorded to each OFFICIAL fax transmission will be determined by the FAX machine's stamped date found on the last page of the transmission, unless that date is a Saturday, Sunday or Federal Holiday with the District of Columbia, in which case the OFFICIAL date of receipt will be the next business day.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Brett Nelson whose telephone number is (703) 306-3219.

If the examiner can not be reached, inquiries can be directed to Primary Examiner Lynette F. Smith whose telephone number is (703) 308-3909 or Supervisory Patent Examiner Donald E. Adams whose telephone number is (703) 308-0570.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

NELSON/bn  
May 13, 1998

*Lynette F. Smith*  
LYNETTE F. SMITH  
PRIMARY EXAMINER  
GROUP 1800